

CERTIFICATE OF MAILING

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ELI LILLY AND COMPANY

By

K. B. Rhodes

Date

*1-9-01*RECEIVED
JAN 23 2001
TECH CENTER 1600/2900PATENT APPLICATIONIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Hermeling, Ronald N., et al.

Serial No. : 09/209,799

Filed : December 11, 1998

For : Glucagon-Like Peptide-1
Crystals

Docket No. : X-10242

Group Art Unit:
1653Examiner:
F. Moezie

RECEIVED

JAN 22 2001

Assistant Commissioner for Patents

Washington, D. C. 20231

TECH CENTER 1600/2900

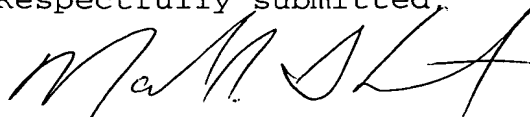
Sir:

On November 22, 2000, at the request of the Examiner, Applicants filed a supplementary response to the Examiner's final rejection. After receiving the response, the Examiner notified Applicant's attorney that an updated sequence listing was missing from the file. An updated sequence listing, however, was submitted with the November 22, 2000 response and was entered by the Office. Recently, Applicants received a faxed copy of an error report associated with the November 22 sequence listing. Applicants have corrected the error and have submitted another copy of the sequence listing.

Enclosed herewith are:

- 1) a copy of the faxed error report;
- 2) a computer-readable copy of the Sequence Listing pursuant to 37 C.F.R. 1.821(e);
- 3) a paper copy of the Sequence Listing pursuant to 37 C.F.R. 1.821(c); and
- 4) an affirmation pursuant to 37 C.F.R. 1.821(f).

Respectfully submitted,



Mark J. Stewart
Attorney for Applicants
Registration No. 43,936
Phone: 317-276-0280

Eli Lilly and Company
Patent Division/MJS
Lilly Corporate Center
Indianapolis, Indiana 46285

January 9/2001

RAW SEQUENCE LISTING ERROR REPORT

BIOTECHNOLOGY
SYSTEMS
BRANCH

FAX: 317-276-5172

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer-readable form:

Application Serial Number 09/209,799 B
Source: 1653
Date Processed by STIC: 12-08-00

JAN 17 2001

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS. PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY, or
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT WITH A NOTICE TO COMPLY.
FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin30help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE (SEE BELOW)

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows-based software program employing a logic and intuitive user interface to check whether a sequence listing is in compliance with formal and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§ 1.821 - 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST-25. Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be downloaded from the USPTO website at the following address:

<http://www.uspto.gov/web/offices/pac/checker>

Raw Sequence Listing Error Summary

ERROR DETECTED SUGGESTED CORRECTION

 SERIAL NUMBER: 09/209,799B

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 Wrapped Nucleics The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 2 Wrapped Aminos The amino acid number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 3 Incorrect Line Length The rules require that a line not exceed 72 characters in length. This includes spaces.
- 4 Misaligned Amino Acid Numbering The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
- 5 Non-ASCII This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
- 6 Variable Length Sequence(s) contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and indicate in the (k) feature section that some may be missing.
- 7 PatentIn ver. 2.0 "bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s) . Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies primarily to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 8 Skipped Sequences (OLD RULES) Sequence(s) missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS: (Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION: SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(III) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).
- 9 Skipped Sequences (NEW RULES) Sequence(s) missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 10 Use of n's or Xaa's (NEW RULES) Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 11 Use of <213> Organism (NEW RULES) Sequence(s) are missing this mandatory field or its response.
- 12 ✓ Use of <220> Feature (NEW RULES) Sequence(s) are missing the <220> Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
- 13 PatentIn ver. 2.0 "bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk.

1653

RAW SEQUENCE LISTING

DATE: 12/08/2000

PATENT APPLICATION: US/09/209,799B

TIME: 10:05:40

Input. Set : A:\X-10242.txt

Output. Set: N:\CRF3\12082000\I209799B.raw

3 <110> APPLICANT: Beschling, Ronald
 4 Hoffmann, James
 5 Narasimhan, Chakravarthy
 7 <120> TITLE OF INVENTION: GLUCAGON-LIKE PEPTIDE-1 CRYSTALS
 9 <130> FILE REFERENCE: X-10242
 C--> 11 <140> CURRENT APPLICATION NUMBER: US/09/209,799B
 C--> 12 <141> CURRENT FILING DATE: 1998-12-11
 14 <160> NUMBER OF SEQ ID NOS: 7
 16 <170> SOFTWARE: Patentia version 3.0
 18 <210> SEQ ID NO: 1
 19 <211> LENGTH: 31
 20 <212> TYPE: PRT
 21 <213> ORGANISM: Homo sapiens
 23 <400> SEQUENCE: 1
 25 His Ala Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Glu Gly
 26 1 5 10 15
 20 Gln Ala Ala Lys Glu Phe Ile Ala Trp Leu Val Lys Gly Arg Gly
 29 20 25 30
 31 <210> SEQ ID NO: 2
 32 <211> LENGTH: 31
 33 <212> TYPE: PRT
 34 <213> ORGANISM: Artificial/Unknown
 36 <220> FEATURE:
 37 <221> NAME/KEY: VARIANT
 38 <222> LOCATION: (1)..(1)
 39 <223> OTHER INFORMATION: Xaa at position 1 is L-histidine, D-histidine, desamino-histidine
 40
 43 <220> FEATURE:
 44 <221> NAME/KEY: VARIANT
 45 <222> LOCATION: (2)..(2)
 46 <223> OTHER INFORMATION: Xaa at position 2 is Ala, Gly, Val, Thr, Met, Ile, and alpha-meth
 47 Y
 50 <220> FEATURE:
 51 <221> NAME/KEY: VARIANT
 52 <222> LOCATION: (15)..(15)
 53 <223> OTHER INFORMATION: Xaa at position 15 is Glu, Gln, Ala, Thr, Ser, and Gly
 56 <220> FEATURE:
 57 <221> NAME/KEY: VARIANT
 58 <222> LOCATION: (21)..(21)
 59 <223> OTHER INFORMATION: Xaa at position 21 is Glu, Gln, Ala, Thr, Ser, and Gly
 62 <220> FEATURE:
 63 <221> NAME/KEY: VARIANT
 64 <222> LOCATION: (31)..(31)
 65 <223> OTHER INFORMATION: Xaa at position 31 is NH2 and Gly-OH
 68 <400> SEQUENCE: 2
 W--> 70 Xaa Xaa Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Xaa Gly
 71 1 5 10 15

Missing mandatory <220>
 <223> feature to explain the
 source of genetic material in the
 artificial
 or
 unknown
 sequence.

See # 12

on Error

Summary
Sheet.

The types of errors shown exist throughout the Sequence Listing. Please check subsequent sequences for similar errors.

RAW SEQUENCE LISTING

DATE: 12/08/2000

PARENT APPLICATION: US/09/209,799B

TIME: 10:00:40

Input Set : A:\X-10242.txt

Output Set: N:\CRF3\12081000\1209799B.raw

W--> 73 Gln Ala Ala Lys Xaa Phe Ile Ala Trp Leu Val Lys Gly Arg Xaa
74 20 25 30

76 <210> SEQ ID NO: 3

77 <211> LENGTH: 29

78 <212> TYPE: PRP

79 <213> ORGANISM: Artificial/Unknown

81 <220> FEATURE:

82 <221> NAME/KEY: VARIANT

83 <222> LOCATION: (28)..(29)

84 <223> OTHER INFORMATION: Xaa at position 28 is Lys or absent

87 <220> FEATURE:

88 <221> NAME/KEY: VARIANT

89 <222> LOCATION: (29)..(29)

90 <223> OTHER INFORMATION: Xaa at position 29 is Gly or absent; and, if Xaa at position 28 is

94 <400> SEQUENCE: 3

96 His Ala Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Glu Gly

97 1 5 10 15

W--> 99 Gln Ala Ala Lys Glu Phe Ile Ala Trp Leu Val Xaa Xaa
100 20 25

102 <210> SEQ ID NO: 4

103 <211> LENGTH: 31

104 <212> TYPE: PRP

105 <213> ORGANISM: Artificial/Unknown

107 <220> FEATURE:

108 <221> NAME/KEY: VARIANT

109 <222> LOCATION: (1)..(1)

110 <223> OTHER INFORMATION: Xaa at position 1 is 4-imidazopropionyl, 4-imidazoacetyl, or 4-im

111 1

114 <220> FEATURE:

115 <221> NAME/KEY: VARIANT

116 <222> LOCATION: (20)..(20)

117 <223> OTHER INFORMATION: Xaa at position 20 is Lys or Arg

120 <220> FEATURE:

121 <221> NAME/KEY: VARIANT

122 <222> LOCATION: (31)..(31)

123 <223> OTHER INFORMATION: Xaa at position 31 is Gly-OH or NH2

126 <400> SEQUENCE: 4

W--> 128 Xaa Ala Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Glu Gly
129 1 5 10 15

W--> 131 Gln Ala Ala Xaa Glu Phe Ile Ala Trp Leu Val Lys Gly Arg Xaa
132 20 25 30

134 <210> SEQ ID NO: 5

135 <211> LENGTH: 31

136 <212> TYPE: PRP

137 <213> ORGANISM: Artificial/Unknown

139 <220> FEATURE:

140 <221> NAME/KEY: VARIANT

141 <222> LOCATION: (2)..(2)

142 <223> OTHER INFORMATION: Xaa at position 2 is Val

RAW SEQUENCE LISTING

DATE: 12/08/2000

PATENT APPLICATION: US/09/209,799B

TIME: 10:05:40

Input Set : A:\X-10242.txt

Output Set: N:\CRF3\12082000\I209799B.raw

145 <400> SEQUENCE: 5
W--> 147 His Xaa Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Glu Gly
148 1 5 10 15
150 Gln Ala Ala Lys Glu Phe Ile Ala Trp Leu Val Lys Gly Arg Gly
151 20 25 30
153 <210> SEQ ID NO: 6
154 <211> LENGTH: 29
155 <212> TYPE: PRT
156 <213> ORGANISM: Artificial/Unknown
158 <220> FEATURE:
159 <221> NAME/KEY: VARIANT
160 <222> LOCATION: (13)..(13)
161 <223> OTHER INFORMATION: Xaa at position 13 is Glu, Glu, Ala, Thr, Ser or Gly
164 <220> FEATURE:
165 <221> NAME/KEY: VARIANT
166 <222> LOCATION: (19)..(19)
167 <223> OTHER INFORMATION: Xaa at position 19 is Glu, Gln, Ala, Thr, Ser or Gly
170 <220> FEATURE:
171 <221> NAME/KEY: VARIANT
172 <222> LOCATION: (29)..(29)
173 <223> OTHER INFORMATION: Xaa at position 29 is Gly or absent
176 <400> SEQUENCE: 6
W--> 178 Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Xaa Gly Gln Ala
179 1 5 10 15
W--> 181 Ala Lys Xaa Phe Ile Ala Trp Leu Val Lys Gly Arg Xaa
182 20 25
184 <210> SEQ ID NO: 7
185 <211> LENGTH: 30
186 <212> TYPE: PRT
187 <213> ORGANISM: Artificial/Unknown
189 <220> FEATURE:
190 <221> NAME/KEY: VARIANT
191 <222> LOCATION: (19)..(19)
192 <223> OTHER INFORMATION: Xaa at position 19 is Lys or Arg
195 <220> FEATURE:
196 <221> NAME/KEY: VARIANT
197 <222> LOCATION: (30)..(30)
198 <223> OTHER INFORMATION: Xaa at position 30 is Gly or is absent; and Lys at position 27 ma
199 y
202 <400> SEQUENCE: 7
204 Ala Glu Gly Thr Phe Thr Ser Asp Val Ser Ser Tyr Leu Glu Gly Gln
205 1 5 10 15
W--> 207 Ala Ala Xaa Glu Phe Ile Ala Trp Leu Val Lys Gly Arg Xaa
208 20 25 30

VERIFICATION SUMMARY

DATE: 12/08/2000

PATENT APPLICATION: US/09/209,799B

TIME: 10:05:41

Input Set : A:\X-10242.txt

Output Set: N:\CRF3\12082000\1209799B.raw

L:11 M:270 C: Current Application Number differs. Replaced Current Application Number
L:12 M:271 C: Current Filing Date differs. Replaced Current Filing Date
L:70 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:2
L:73 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:2
L:99 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:3
L:120 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:4
L:131 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:4
L:147 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:5
L:170 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:6
L:181 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:6
L:207 M:341 W: (46) "n" or "Xaa" used. for SEQ ID#:7